K122562

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Applicant

Name: E-TENG TECHNOLOGY INC.
Address: No. 108, Masu Rd., Wanli Dist., New Taipei City, 207, Taiwan
Contact person: Mr. Y. W. Chen, Design Manager
Phone: +886-2-2492-3888
Fax: +886-2-2492-3888

Date prepared: Aug. 08, 2013

AUG 09 2013

Device

Trade name: EOR 1 Stand-Up Power Wheelchair
Common (generic) name: Standup wheelchair
Classification name: Standup wheelchair
Medical specialty (Panel): Physical Medicine Device
Regulation number: 890.3900
Product Code: IPL
Classification: Class II

Predicate devices

Trade name: LEVO Combi
Manufacture: LEVO AG
510(k) number: K030893
Regulation number: 890.3900
Product Code: IPL
Classification: Class II

Intend use of device

The device is a product which change people's position from standing to sitting or sitting to standing and any position in between. The product provides indoor and outdoor mobility on surfaces like tar, grass and gravel. However, it should not be driven in the standing position on uneven ground.

Device description:

The device changes people's position in/from seating or/to standing but also any position in between. It provides indoor and outdoor mobility on surfaces like tar,

grass and gravel. However, it is not allowed to drive in standing position on uneven ground.

The device is powered by a 24 V DC/36 Ah, lead-acid battery, approximate driving range on fully charged battery is up to 32 km(19 miles), depending on use and the terrain the wheelchair is driven on, and which maximum speed is up to 8 km/h (5 mph). The device is middle wheels with motors driven and controlled by the DYNAMIC DX2 controller.

Summary of non-clinical tests

The EOR 1 standup power wheelchair complied with the requirements of ISO 7176-1, ISO 7176-2, ISO 7176-3, ISO 7176-4, ISO 7176-5, ISO 7176-6, ISO 7176-9, ISO 7176-10, ISO 7176-11, ISO 7176-13, ISO 7176-14, ISO 7176-15, ISO 7176-16, ISO 7176-21, ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 14971, ANSI/RESNA WC.Vol.1 Sec. 7, Sec. 8 and Sec. 20, CISPR 11, IEC 61000-4-2, IEC 61000-4-3.

Statement of substantial equivalence

The EOR 1 standup power wheelchair and the predicate device all are the products which change a people position not only from sitting to standing and standing to sitting but also reclines backrest and lifts leg positions. They provide indoor and outdoor mobility.

They have the same user interface while there are minor differences between the devices do not alter the intended use function and use of the device. Moreover, the non-clinical tests and the predicate comparisons demonstrate that these differences in their technological characteristics do not raise any questions as to the safety and effectiveness, therefore the EOR 1 standup powered wheelchair is substantially equivalent to the predicate device.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, E-TENG TECHNOLOGY INC. concludes that, EOR 1 standup power wheelchair is substantially equivalent to predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 9, 2013

E-TENG Technology, Inc
% Ms. Junnata Chang
16-F2 (16A), No. 462, Sec. 2
ChongDe Rd., Betin Dist.
Taichung,
China (Taiwan) 406

Re: K122562
Trade Name: E-TENG Model EOR 1
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup Wheelchair
Regulatory Class: Class II
Product Code: IPL
Dated: June 20, 2013
Received: July 2, 2013

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122562

Device Name: EOR 1 Stand-Up Power Wheelchair

Indications For Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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